

## REMARKS

Claims 1 – 30 are pending in this application.

Claims 1 – 8 and 17 – 23 have been rejected.

Claims 9 – 16 and 24 – 30 have been withdrawn by the Examiner.

### Election/Restriction

Notice is taken of the indication by the Examiner that claims 9 – 16 and 24 – 30 have been withdrawn being unrelated to claims 1 – 8 and 17 – 23, and as such are patentably distinct with respect to each other under MPEP 802.01, part II.

### Rejections Under 35 U.S.C. § 102

Claims 1 – 4, 8 and 17 – 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,381,013 (“Dutcher ‘013”). These rejections are respectfully traversed.

Dutcher ‘013 discloses a “J” stylet wire. Stylet wire 30 is inserted into stylet housing 36 (Figures 2 and 3). Distal end 34 of stylet wire 30 is bent at reference point 32 (column 3, lines 42 – 53). Distal end 34 of stylet 30 does not come into contact with torque receiving body 28 (column 3, lines 45 – 49). Stylet housing 36 has coil 40 and torque transmission tool 44 which interacts with torque receiving body 28 and which is of a smaller diameter than coil 40 (column 3, line 63 – column 4, line 5). But Dutcher ‘013 does not show, disclose or suggest that stylet wire 30 is tapered within a curved intermediate segment. Rather, it is stylet housing 36 which has a decrease in diameter, and that is tapered at the transmission tool at the distal end.

By contrast, claims 1 and 17 recite a pre-formed j-shape stylet having, among other components, a taper zone extending within a curved intermediate segment having a gradual decrease in diameter (claim 1, lines 8 – 9; claim 17, lines 8 – 9). The j-shape stylet inserted into a medical electrical lead (claim 1, lines 10 – 12; claim 17, line 1). The

Office Action identifies stylet wire 30 as the j-shape stylet and stylet housing 36 as the electrical lead. In fact, Dutcher '013 discloses the exact opposite of the subject matter recited in claims 1 and 17, in that it is the stylet housing 36, a.k.a. the electrical lead, which has a decrease in diameter, and not the stylet wire 30. Stylet wire 30 is not depicted as being tapered in any way. Moreover, the decrease in diameter in the stylet housing 36 is at the far distal end, and not in an intermediate portion.

Dutcher '013 does not show, disclose or suggest a pre-formed j-shape stylet having, among other components, a taper zone extending within a curved intermediate segment having a gradual decrease in diameter. Rather, Dutcher '013 discloses a stylet housing 36, identified as equivalent to an electrical lead, with a decrease in diameter at a distal end. Thus, Dutcher '013 does not show, disclose or suggest all of the subject matter of claims 1 and 17. It is respectfully submitted that the rejections of claims 1 and 17 under 35 U.S.C. 102(b) as being anticipated by Dutcher '013 are improper and should be withdrawn.

Claims 2 – 4 and 8 depend from claim 1 and claims 18 – 20 depend from claim 17, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 2 – 4, 8 and 18 – 20 recite additional patentable subject matter. Because the rejections of claims 1 and 17 are improper, and because of the additional patentable subject matter, it is respectfully submitted that the rejections of claims 2 – 4, 8 and 18 – 20 under 35 U.S.C. 102(b) as being anticipated by Dutcher '013 are improper and should be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

#### Dutcher '013 in view of Hartley et al '141

Claims 5 – 7 and 21 – 23 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,381,013 (“Dutcher '013”) in view of U.S. Patent Publication No. 2004/0073141 (“Hartley et al '141”). These rejections are respectfully traversed.

The above discussion of claims 1 and 17 and of Dutcher '013 is incorporated here in its entirety.

Hartley et al '141 discloses a guide wire. Guide wire 1 is variably stiff within various zones (paragraph [0054]). A tapered proximal tip is shown in Figure 15 (paragraph [0077]). But Hartley et al '141 does not show, disclose or suggest a pre-formed j-shape stylet having, among other components, a taper zone extending within a curved intermediate segment having a gradual decrease in diameter. While Hartley et al '141 has varying stiffness, Hartley et al '141 does not show, disclose or suggest being pre-formed. Nor does Hartley et al '141 show, disclose or suggest a taper extending within a curved intermediate segment. Rather, a taper is only disclosed at a proximal tip.

By contrast, claims 1 and 17 recite a pre-formed j-shape stylet having, among other components, a taper zone extending within a curved intermediate segment having a gradual decrease in diameter (claim 1, lines 8 – 9; claim 17, lines 8 – 9). The j-shape stylet inserted into a medical electrical lead (claim 1, lines 10 – 12; claim 17, line 1). Neither Dutcher '013 nor Hartley et al '141 show, disclose or suggest this subject matter, as Dutcher '013 does not show, disclose or suggest a stylet with a taper at all, and Hartley et al '141 does not show, disclose or suggest a taper in an intermediate segment, instead showing only a tapered proximal tip. Thus, claims 1 and 17 are not rejectable over Dutcher '013 in view of Hartley et al '141.

Claims 5 – 7 depend from claim 1 and claims 21 – 23 depend from claim 17, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 5 – 7 and 21 – 23 recite additional patentable subject matter. Because claims 1 and 17 are not rejectable, and because of the additional patentable subject matter, it is respectfully submitted that the rejections of claims 5 – 7 and 21 – 23 under 35 U.S.C. 103(a) as being obvious over Dutcher '013 in view of Hartley et al '141 are improper and should be withdrawn.

Williams '482

Claims 1 – 8 and 17 – 23 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,498,482 (“Williams ‘482”). These rejections are respectfully traversed.

Williams ‘482 discloses a transvenous pacing lead having an improved stylet. The stylet has a taper which results in a soft tip that “complies with the curvatures and bends of transvenous pacing lead” (column 1, lines 53 – 55). The stylet is configured to “allow for easy insertion and control around the curves and bends of the lead” (column 3, lines 19 – 20). Thus, Williams ‘482 discloses that the stylet should conform to the curves and bends of the lead. As such, not only does Williams ‘482 not show, disclose or suggest a stylet with a pre-formed j-shape that imparts a similar curve to the lead, Williams ‘482 teaches away from a stylet with a pre-formed j-shape that imparts a similar curve to the lead by specifically disclosing that it is the stylet that conforms to the lead.

By contrast, claims 1 and 17 recite a pre-formed j-shape stylet that imparts a similar curve to the lead. Williams ‘482 does not show, disclose or suggest a pre-formed j-shape stylet that imparts a similar curve to the lead, and, as has been noted above, actually teaches away from a pre-formed j-shape stylet by asserting that the stylet conforms to the lead. Thus, Williams ‘482 does not show, disclose or suggest all of the subject matter of claims 1 and 17.

The Office Action asserts “it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stylet of Williams with a j-shaped stylet in order to yield the predictable results of reducing trauma to the arterial system.” It is respectfully submitted that this statement does not capture the requirements to show obviousness under the Examination Guidelines after the *KSR* decision. There has been no finding of each claimed element in the prior art. There has been no finding of a simple substitution of some components with other components. Nor has been no finding of a base device that has been improved in the same way. There has been no finding that a base device has been “improved” by a technique known in the art. There is no showing that it would have been obvious to try a pre-formed j-shape stylet. There has been no finding that the prior art included a similar or analogous device.

And finally, not only has there not been a finding of a teaching, suggestion or motivation in Williams '482 for a pre-formed j-shape stylet that imparts a similar curve to the lead, Williams '482 teaches away from that by asserting that the stylet conforms to the shape of the lead.

Williams '482 does not show, disclose or suggest all of the subject matter of claims 1 and 17. Nor does Williams '482 meet any of the Examination Guidelines for determining obviousness under *KSR*. Thus, it is respectfully submitted that the rejections of claims 1 and 17 under 35 USC § 103(a) as being obvious over Williams '482 are improper and should be withdrawn.

Claims 2 – 8 each contain additional patentable subject and depend from claim 1, while claims 18 – 23 each contain additional patentable subject matter and depend from claim 17, and as such incorporate all of the subject matter of the claims from which they depend. Because claims 2 – 8 and 18 – 23 contain additionally patentable subject matter and because the rejections of claims 1 and 17 are improper, it is respectfully submitted that the rejections of claims 2 – 8 and 18 – 23 under 35 USC § 103(a) as being obvious over Williams '482 are improper and should be withdrawn.

## Summary

In view of the amendments made and arguments presented, claims 1 – 30 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.

## Correspondence

**All correspondence should continue to be directed to:**

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Respectfully Submitted,



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